

N0489

A Phase II Study of Epratuzumab, Rituximab (ER)-CHOP for Patients With Previously Untreated Diffuse Large B-Cell Lymphoma

ClinicalTrial.gov Identifier: NCT00301821

Study Background

Trial Description

RATIONALE: Monoclonal antibodies, such as epratuzumab and rituximab, can block cancer growth in different ways. Some block the ability of cancer cells to grow and spread. Others find cancer cells and help kill them or carry cancer-killing substances to them. Drugs used in chemotherapy, such as cyclophosphamide, doxorubicin, vincristine, and prednisone, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving monoclonal antibody therapy together with chemotherapy may kill more cancer cells.

PURPOSE: This phase II trial is studying how well giving monoclonal antibody therapy together with combination chemotherapy works in treating patients with stage II, stage III, or stage IV diffuse large B-cell lymphoma.

Arms:

Epratuzumab + Rituximab + CHOP: (Experimental): One arm open label.

Objectives:

Primary

- Assess the efficacy of epratuzumab and rituximab in combination with cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (CHOP), as measured by 12-month, event-free survival, in patients with previously untreated stage II, III, or IV diffuse large B-cell lymphoma.
- Assess the use of positron emission tomography (PET) scan routinely early in treatment and after completion of treatment.
- Assess the functional response rate (complete response, partial response, or stable disease by CT scan and PET negative) in patients treated with this regimen.
- Assess the safety of this treatment regimen.

Publication Information:

Analysis Type: Primary

Pubmed ID: 21673350

Citation: Blood. 2011 Oct 13;118(15):4053-61. doi: 10.1182/blood-2011-02-336990.
Epub 2011 Jun 14.

Associated Datasets: NCT00301821-D1-Dataset (outcome), NCT00301821-D2-Dataset (events)

Dataset Information:

Dataset Name: NCT00301821-D2-Dataset.csv (events)

Description: Dataset NCT00301821-D2-Dataset.csv (events) is one of 2 datasets associated with PubMed ID 21673350. This dataset contains information that will allow you to reproduce the adverse events reported.

In Table 2, eleven patients were reported as having reported Dyspnea. The data provided includes 10 patients reporting 11 instances of Dyspnea.

NCT00301821-D2 Dataset.csv (events) Data Dictionary:

LABEL	NAME	elements	comments
Patient Reference	PATREF		Deidentified patient reference
Arm	ARM	A	Arm is missing from Baseline events.
Body System	BODYSYS		
Cycle	CYCLE		
Grade	GRADE	4, 2, 1, 3, 5	CTCAE v3.0
Relationship Study Meds	REL_SMED	DEFINITE, POSSIBLE, PROBABLE, UNLIKELY, NOT RELATED,	Missing means the data was not collected
	TOXCODE		MedDRA Code v 6.0
Toxicity	TOXICITY		Literal coded value